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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/325,095	06/03/1999	IAN D. HILES	LUD5246.4JEL	2392

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/325,095

Applicant(s)

HILES ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 51-58,60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 51-58,60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 April 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. The amendment filed April 9, 2003 has been entered. Examiner acknowledges amendments to the specification. Claims 1-50 and 59 have been canceled. Claim 51 has been amended. Claims 51-58 and 60-61 are under consideration in this office action.

Drawings

2. The drawings were received on April 9, 2003 are acceptable.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The written description rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons already of record.

Claim 51 is now to draw to a method for determining expression of a gene that encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA and is selected from the group consisting of (a) the nucleotide sequence set forth in SEQ ID NO:32; (b) the nucleotide sequence set forth in SEQ ID NO:35; and (c) the nucleotide sequence which hybridizes to the complement of at least one of (a) and (b), at the recited conditions and determining said hybridization as a determination of expression of said gene. The specification describes the hybridization method as a separate method from the PCR method, therefore there is no written description of this entire method as being capable of determining expression of the gene.

The specification and claims lack sufficient written description of a method for determining expression of a gene that encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA and is selected from the group consisting of (a) the nucleotide sequence set forth in SEQ ID NO:32; (b) the nucleotide sequence set forth in SEQ ID NO:35; and (c) the nucleotide sequence which hybridizes to the complement of at least one of (a) and (b), at the recited conditions and determining said hybridization as a determination of expression of said gene. There is no description of an entire method that describes hybridization as a method of determining gene expression. There appears to be no support in the specification for contacting a sample

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with a nucleic acid molecule that hybridizes to a transcript of the gene and determines that hybridization equates to expression of the gene in the manner now claimed.

Moreover, the claim is drawn to a sample, however the sample has to be RNA, since DNA cannot discriminate the transcript of said gene. Normally, mRNA leads to cDNA which leads to amplification, however neither the specification nor claims describe such a method, thus the written description is inadequate since the claim method is not described. The nucleotide sequence of (c) requires hybridization to the complement, however the complement is not required to be a coding variant, therefore the matter has not been adequately described.

Claim 55 is drawn to the method of claim 51 wherein said method should further comprise polymerase chain reaction. There is written description of the claim method that works using mRNA as apart of the amplification process. Moreover, there is no primer in claim 51 which would allow the polymerase chain reaction to operate. There is not adequate written description within the specification to support the instant claim.

Thus, in the absence of the necessary reagents and steps required for a method for determining expression of a gene that encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA and is selected from the group at the recited low stringency conditions and determining said hybridization as a determination of expression of said gene, it fails to meet the written description requirements. In view of these considerations, a person of skill in the art would not have viewed the teachings of

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the specification sufficient to show that Applicants were in possession of the claimed method as instantly asserted. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph.

New Matter Rejection

4. The new matter rejection of claims 51-58 and 60-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained.

The claims are drawn to a method for determining expression of a gene that encodes a human polypeptide that has PI3 kinase activity and a molecular weight of about 110 kD comprising contacting a sample with a nucleic acid molecule which hybridizes specifically to a transcript of said gene wherein said transcript is RNA or cDNA and is selected from the group consisting of (a) the nucleotide sequence set forth in SEQ ID NO:32; (b) the nucleotide sequence set forth in SEQ ID NO:35; and (c) the nucleotide sequence which hybridizes to the complement of at least one of (a) and (b), at the recited low stringency conditions and determining said hybridization as a determination of expression of said gene.

Applicants' arguments are that if the transcript is present, then the gene is present and if the transcript is present then the gene has been expressed, thus the claims do not incorporate new matter. It is the examiner's position that basic molecular

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biology concepts do not prevent new matter from being incorporated into the instant claims.

Because of the low or reduced stringency conditions of the instant claims, the method allows even distantly related genes to be identified; thus the method will include imperfectly matched sequences to be determined. Thus the method will find more than just genes which encode a human polypeptide that has PI3 kinase activity and a molecular weight of about 110kD as determined by SDS page. Moreover, there appears to be no teaching within the specification that the determination of hybridization alone will determine the expression of said gene or the presence of said gene in view of the conditions recited by the claims. Applicants' argument failed to point to by page and line number for support of said determinations. The specification teaches hybridization techniques and the expression of particular proteins, however the specification fails to teach that based solely upon hybridization can an artisan determine the expression of said gene or its presence. Therefore, the claimed subject matter is not within the scope of the subject matter disclosed within the specification, thus the rejection drawn to claiming new matter is maintained.

5. The rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap and incomplete method between the claimed steps is maintained for reasons already of record.

Contrary to applicants arguments which only address the label issue, claim 51 is drawn to methods for determining expression of a gene or for determining if a cell contains a gene wherein the gene encodes a human polypeptide that has PI3 kinase activity and determine said hybridization as a determination of expression of said gene or the presence of said gene. However, the methods are incomplete and lack steps for determining the expression of a gene. The method still fails to recite how the hybridized product equates to the determination of expression. There is no positively recited step to determine expression of said gene. Thus the rejection is maintained.

6. The rejection of claims 51-58 and 60-61 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons already of record. Applicants assert that in view of the previous arguments the rejection should be withdrawn, however the preamble of claim 51 is drawn to a method for determining expression of a gene. However there are no steps within the method which teach how to determine the expression of a gene. The claims lack a positive recitation of method steps that recite such determinations. For instance there is no step for the amplification of the hybridized nucleic acid molecule by PCR, there is no step for the transient expression of the product, no immunoprecipitation step, there is no step which determines whether the cDNA encodes a protein with a molecular weight of 110 that possesses PI-3 kinase activity. Finally, there is no step which correlates the determination of hybridization to the determination of expression or the presence of said

gene. Therefore, the goal of the preamble is not commensurate with the steps of the method and the rejection is maintained.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *JN*

January 8, 2004

LFS
LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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